



Atty. Dkt. No. 067286-0278

**THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: James C. KENNEDY et al.

Title: PHOTOCHEMOTHERAPEUTIC METHOD  
USING 5-AMINO LEVULINIC ACID AND  
OTHER PRECURSORS OF ENDOGENOUS  
PORPHYRINS

Appl. No.: 10/605,826

Filing Date: 10/29/2003

Examiner: Unassigned

Art Unit: 1617

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Mail Stop PATENT APPLICATION  
Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Sir:

Applicants submit herewith on Form PTO/SB/08 a listing of the documents cited by or submitted to the U.S. PTO in parent application Serial No. 09/816,329, filed 03/26/2001. As provided in 37 CFR §1.98(d), copies of the documents are not being provided since they were previously submitted to the United States Patent & Trademark Office in the above-identified parent application.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

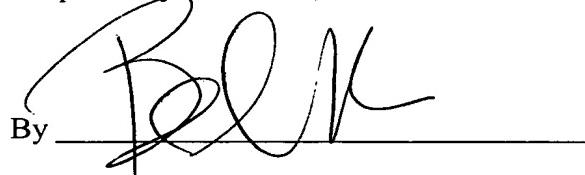
**RELEVANCE OF EACH DOCUMENT**

The relevance of the listed documents is explained in the parent application.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

By 

Date 26 March 2004

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INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 6

Complete if Known

Application Number	10/605,826
Filing Date	10/29/2003
First Named Inventor	James C. Kennedy
Group Art Unit	1617
Examiner Name	Unassigned

MAR 26 2004

U.S. PATENT &amp; TRADEMARK OFFICE

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
A1	5,211,938			KENNEDY et al.	05/93	
A2	5,219,878			RINGUET et al.	06/93	
A3	5,163,990			REBEIZ	11/92	
A4	5,200,427			REBEIZ et al.	04/93	
A5	5,079,262			KENNEDY et al.	01/92	
A6	5,234,940			KENNEDY et al.	08/93	
A7	4,772,681			FUKUDA et al.	09/88	
A8	4,977,177			BOMMER et al.	12/90	
A9	5,004,811			BOMMER et al.	04/91	
A10	5,127,938			REBEIZ	07/92	
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A12	4,932,934			DOUGHERTY et al.	06/90	
A13	5,425,728			TANKOVICH	06/95	
A14	5,226,907			TANKOVICH	07/93	
A15	5,423,803			TANKOVICH et al.	06/95	
A16	5,484,803			RICHTER	01/96	
A17	5,955,490			KENNEDY, et al.	09/99	
A18	5,705,518			RICHTER et al.	06/98	

## FOREIGN PATENT DOCUMENTS

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
A19	EP	0 233 701				08/87		
A20	WO	95/07077				03/95		

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	A21	WO	93/08715		05/93		
	A22	WO	91/01727		02/91		
	A23	WO	95/31189		11/23/95		
	A24	WO	94/06424		3/31/94		
	A25	WO	95/05813		3/2/95		
	A26	WO	93/20810		10/28/93		
	A27	WO	94/12239		6/9/94		

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	A28	BOEHNCKE, et al., Treatment of Psoriasis by Topical Photodynamic Therapy with Polychromatic Light, <i>The Lancet</i> , 343:801, March 1994					
	A29	FUKUDA et al., Photodynamic Action of Endogenously synthesized Porphyrins from Aminolevulinic, <i>Int. J. Biochem.</i> , 25:10; 1395-98, 1993					
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	A32	GRANT et al., Photodynamic Therapy of Normal Rat Arteries After Photosensitisation Using . . . , <i>Br. J. Cancer</i> , 70:72-78, 1994					
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				Group Art Unit	1617
				Examiner Name	Unassigned
				Attorney Docket Number	067286-0278

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	A36	KENNEDY et al., "Topical Photodynamic Therapy For Cancers Of The Skin", <i>Canadian Dermatology Association Journal</i> , Vol. 5, No. 3, pp. 45-47, (1991)	
	A37	BICKERS et al., "Biosynthesis of Porphyrins in Mammalian Skin And In The Skin Of Porphyric Patients", <i>The Journal Investigative Dermatology</i> , Vol. 68:5-9, (1977)	
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	A39	MALIK et al., "Destruction of Erythroleukaemic Cells By Photoactivation Of Endogenous Porphyrins", <i>Br. J.Cancer</i> , Vol. 56:589-595, (1987)	
	A40	MALIK et al., "The Role Of Hemin In The Regulation Of Heme Synthesis By Fetal Mouse Liver Erythroblasts In Culture", <i>Exp. Hemat.</i> , Vol. 7, No. 4, pp. 183-188, (1979)	
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	A48	HUA et al., "Effectiveness of δ-Aminolevulinic Acid-Induced Protoporphyrin As A Photosensitizer - For Photodynamic Therapy In Vivo", <i>Cancer Research</i> , Vol. 55:1723-1731, (1995)	
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Sheet 4 of 6

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First Named Inventor	James C. Kennedy
Group Art Unit	1617
Examiner Name	Unassigned

Attorney Docket Number 067286-0278

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	A50	KOENIG et al., "In Vivo Photoproduct Formation During PDT With ALA-Induced Endogenous Porphyrins", <i>J. Photochem. Photobiol. B: Biol.</i> , Vol. 18:287-290, (1993)	
	A51	VAN HILLEGERSBERG et al., "Current Status of Photodynamic Therapy In Oncology", <i>Drugs</i> , Vol. 48(4):510-527, (1994)	
	A52	YANG et al., "Photodynamic Ablation of Early Pregnancy in the Rat With 5-Aminolevulinic Acid: A Potential New Therapy For Tubal Ectopic Pregnancy in the Human", <i>Fertility And Sterility</i> , Vol. 62(5):1060-1065, (1994)	
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	A54	FUKUDA et al., "Tumor-Localizing Properties of Porphyrins, in vitro Studies Using The Porphyrin Precursor, Aminolevulinic Acid, In Free And Liposome Encapsulated Forms", <i>Drug Des. Deliv.</i> , Vol.5:133-139, (1989)	
	A55	YANG et al., "Intrauterine 5-Aminolevulinic Acid Induces Selective Fluorescence And Photodynamic Ablation Of The Rat Endometrium", <i>Photochemistry And Photobiology</i> , Vol. 57(5):803-807, (1993)	
	A56	GRANT et al., "Photodynamic Therapy of Oral Cancer: Photosensitisation With Systemic Aminolevulinic Acid", <i>The Lancet</i> , Vol. 342:147-148, (1993)	
	A57	LOH et al., "Oral Versus Intravenous Administration Of 5-Aminolevulinic Acid For Photodynamic Therapy", <i>Br. J. Cancer</i> , Vol. 68:41-51, (1993)	
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	A59	KENNEDY, "Photochemotherapy - Clinical Aspects", Department of Oncology and Pathology, Photosensitisation. Edited by G. Moreno et al., pp. 453-463, (1988)	
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Sheet	5	of	6		

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	A62	BERLIN et al., "Normal Pathways, Studied With The Aid of N", <i>The Metabolism of δ-Aminolaevulinic Acid</i> , Vol.64:80-99,(1956)	
	A63	BRAULT et al., "Fundamental Aspects In Tumor Photochemotherapy: Interactions Of Porphyrins With Membrane Model Systems And Cells", <i>Biochimie</i> , Vol. 68:913-921, (1986)	
	A64	DIVARIS et al., "Phototoxic Damage To Sebaceous Glands And Hair Follicles Of Mice After Systemic Journal Administration of 5-Aminolevulinic Acid Correlates With Localized Protoporphyrin IX Fluorescence", <i>American of Patbiology</i> , Vol. 136(4):891-897, (1990)	
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	A71	YANG, et al., "Evidence of Lasting Functional Destruction Of The Rat Endometrium After 5-Aminolevulinic Acid Induced Photodynamic Ablation: Prevention of Implantation", <i>Am. J. Obstet. Gynecol.</i> , Vol. 168(3):995-1001, (1993)	
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